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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01 21 2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/342,024

Applicant(s)

NOLAN ET AL.

Examiner

Gerald G Leffers Jr.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: please see the attached sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see the attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 17, 21, 22, 32, 33, 35 and 38.

Claim(s) rejected: 1, 2, 4-12, 30, 31, 34, 36, 37 and 39.

Claim(s) withdrawn from consideration: 3, 13-16, 18 and 23-29.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Advisory Action Attachment

2(d) cont. Amendment of claim 39, line 10, to read "cells" raises new issues under 112 2nd paragraph concerning antecedent basis for the term.

5(c) cont. Applicants' arguments directed to the amended claims and specification are moot since the amendment has not been entered. It is noted, however, that upon entry of the amendment to the specification to claim dependency from U.S. Application Serial No. 09/103,477, the rejection of claims as obvious over Yamazaki et al will be withdrawn. It is further noted that such an amendment to the specification should also include the claim for priority under 35 U.S.C. 120 to PCT/US99/14447.

With regard to the teachings of Dev patent (i.e. the '710 patent), applicants' response essentially argues: 1) it is the *combination* of the specifically recited low electric field impulse and long pulse length that is the crux of the claimed invention, 2) the proposed claim amendments make clear it is the combination of field strength and pulse duration that is important, 3) the examiner appears to have not given sufficient weight to Applicants' arguments that it is the selection of low field strength within the recited range in combination with the long pulse length in the recited range that is a primary distinguishing factor of the instant invention over the teachings of the '710 patent, 4) although Dev discloses a conventional broad range of pulse conditions and pulse length, Dev does not teach, suggest or otherwise direct those of skill in the art to select Applicants' specific combination of parameters or that selection of the recited combination of parameters would provide the disclosed advantage of minimizing cell death, 5) Dev is absolutely silent with regard to supercoiled DNA, 6) Dr. Dietmar P. Rabussay states in a

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37 C.F.R. 1.132 declaration that, in his opinion, the teachings of Dev are substantially different from those recited in the rejected claims.

The gist of applicants' argument is well understood by the examiner. Applicants continue to argue that Dev does not teach the specific combination of field strength and long pulse length recited in the rejected claims (i.e. 300-600 V/cm in combination with 10-100 milliseconds). It is noted that the proposed amendment to the claims in Paper No. 16, filed 12/27/02, does not further clarify the issue in that the examiner understood that the recited ranges were intended to be in conjunction with one another. The issue then is whether a pair of recited ranges in a methods step taught by the prior art that overlap with applicants' recited range constitute a teaching of specific conditions that fall within, and anticipate, the claimed range.

The declaration by Dr. Rabussay has been considered in full. Dr. Rabussay is correct in asserting that the ranges taught by the '710 patent "lie substantially outside" the claimed range. This does not change the fact that Dev et al teach in their patent that a combination of ranges from 100 V/cm to several kV/cm and 100 microseconds to 100 milliseconds can be used in their invention. Even the preferred ranges taught by Dev, 500 microseconds-10 milliseconds and 500 V/cm-5.0 kV/cm (e.g. column 10, lines 34-36), fall within the parameters recited in the rejected claims. The *opinion* expressed by Dr. Rabussay that the ranges taught by the '710 patent exclude most of the voltage range recited in the rejected claims does not change the fact that the patent does teach those ranges and does anticipate the rejected claims. The *opinion* expressed by Dr. Rabussay that the '710 patent "leads away" or teaches away from the claimed invention is irrelevant. First, Dr. Rabussay is not competent to advise the office on whether a reference legally "teaches away" from the claimed invention. Secondly, the issue of "teaching away" is

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not relevant for a rejection made under 35 U.S.C. 102. Third, there is no teaching away in that Dev does not lead one to expect that the specifically recited combinations of field strength and pulse length would not work. The fact that the parameters used in the example taught by Dev et al do not fall within the ranges recited by the rejected claims is also irrelevant in that Dev, like applicants, is not required to exemplify every specific embodiment encompassed by their teachings. Unless specifically taught otherwise, one of ordinary skill in the art would necessarily expect that a teaching regarding electroporation of plasmid DNAs into a cell encompasses supercoiled DNA since this is the predominant form of plasmid DNA upon preparation by most commonly used methods. For at least the reasons outlined above, applicants' arguments concerning the Dev patent are not persuasive.

Conclusion

The amendment has not been entered. Once perfected, the claim for priority to 09/103,477 will obviate rejections made of Yamazaki et al in the previous office action. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl

Ggl
January 15, 2003

[Signature]
PRIMARY EXAMINER